Assessment of the USEPA Region 3
Laboratory Certification Program for Drinking Water

Conducted by the

Office of Water
Office of Ground Water and Drinking Water
Technical Support Center

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U. S. ENVIRONMENTAL PROTECTION AGENCY

Cincinnati, Ohio 45268

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1. Introduction

The "Manual for the Certification of Laboratories Analyzing Drinking Water" (MCLADW) (Fifth Edition, 2005, EPA 815-R-05-004) requires the U.S. Environmental Protection Agency's Office of Ground Water and Drinking Water (OGWDW) to "review the EPA Regional [drinking water] certification programs annually and evaluate the resources and personnel available in each Region to carry out the certification program." Paper assessments in the form of questionnaires are performed annually with onsite assessments conducted at least triennially.

Primacy States maintain programs for the certification and/or accreditation of laboratories conducting analyses of drinking water compliance samples per federal regulations [40 CFR 142.10(b)(3)(i)]. The Region oversees the Principal State Laboratory (PSL) or PSL network of laboratories in every State that holds primacy. The laboratories may be EPA-certified, National Environmental Laboratory Accreditation Program (NELAP)-accredited or recognized through a reciprocity agreement with another LCP. The Region holds primacy for all non-primacy States and certifies/accredits or recognizes through reciprocity all laboratories used by the non-primacy State. EPA Region 3 (Region 3) oversees the PSL/PSL network in 5 primacy States and certifies the Corps of Engineering Washington Aqueduct Laboratory (WAL) in Washington, DC. In addition, Pennsylvania and Virginia have dual EPA/NELAP programs, where they provide a State Laboratory Certification Program (SLCP) (consistent with the MCLADW) and a drinking water lab accreditation programs (consistent with NELAP program requirements). Region 3 has no Tribal laboratories.

The Region 3 Regional Administrator, Shawn Garvin, has officially delegated Certification Authority to John Pomponio, the Division Director of the Environmental Assessments and Innovation Division (EAID). The implementation of the Region 3 Drinking Water Program is the responsibility of Jon Capacasa, the Division Director of the Water Protection Division (WPD). EAID and WPD are located in the Regional office at 1650 Arch Street, Philadelphia, Pennsylvania 19103-2029. Both Division Directors report directly to the Region 3 Administrator. These Divisions have maintained a strong partnership in the full implementation of the SDWA since promulgation of that Act.

The responsibility within the WPD for SDWA implementation is with the Office of Drinking Water & Source Water Protection. This office has two branches: Drinking Water Branch and the Ground Water and Enforcement Branch. William Arguto is WPD's Drinking Water Branch Chief. The Branch has an EPA Drinking Program Manager for each Region 3 State and Washington, D.C. Region 3 retains primacy for the drinking water program in the District.

Mr. Pomponio appointed Edward (Ed) Messer as the Acting Regional Laboratory Certification Program Manager (LCPM). Mr. Messer is the Office of Analytical Services and Quality Assurance (OASQA) Senior Scientist (OSS) and the Proficiency Testing (PT) Program Manager, and is responsible for onsite assessments of the Region's SLCPs. He receives assistance from George Long, a Senior Environmental Employment Program (SEEP) employee. Region 3's Laboratory Certification Program is located in the Environmental Science Center, 701 Mapes Road, Ft. Meade, Maryland 20755-5350.The Region 3 laboratory and technical services are also housed in OASQA's Environmental Science Center.

The OSS serves as the lead Regional Certification Officer (CO). Mr. Messer has completed EPA's SDWA Certification Officer's training course provided by TSC and is certified for organic chemistry. He also has completed the NELAP/TNI evaluator's course provided by TNI and has experience performing laboratory assessments. The Regional Certification Personnel include:

Immediate Office COs:

George Long (SEEP) (inorganic chemistry)
Ed Messer, Environmental Scientist (organic chemistry)

Technical Services Branch COs:

Jarmael Burman (inorganic chemistry),

Laboratory Branch COs:

Annie Hilliard (SEEP) (microbiology)
Robin Costas (inorganic chemistry)
Joseph Dorsey (inorganic chemistry)
Jennifer Gundersen (organic chemistry)
Adam Molnar (organic chemistry)
David Russell (microbiology)
Susan Warner (organic chemistry)
Eric Graybill (inorganic and organic chemistry; microbiology)

Region 3 utilizes the TSC contractor, Computer Sciences Corporation (CSC), to audit radiochemistry labs. An organizational chart of the Region 3 Regional Laboratory Certification Program (RLCP) is shown in Attachment A.

Judy Brisbin, Jennifer Best, Michella Karapondo and Dan Hautman from OGWDW Technical Support Center (TSC) performed the onsite RLCP assessment (RLCPA), with support from Laurie Potter of the Cadmus Group, Inc. (Cadmus). The RLCPA was held at Region 3's LCP office in Ft. Meade, Maryland on February 5 and 6, 2015.

TSC staff and Cadmus held the opening conference on February 5, 2015. In attendance from the Region were Cynthia Caporale (Associate Director, OASQA), Fred Foreman (Technical Services Branch Chief, OASQA), Mr. Long, and Mr. Messer. Cadmus assisted TSC with the file and documentation review on both days. The exit debrief, which was attended by the same people, took place on February 6, 2015. The RLCPA agenda is shown in Attachment B and the List of Attendees in Attachment C.

2. Regional Oversight of Primacy State Drinking Water Certification/Accreditation Programs

EPA Regions oversee the SLCPs. As stated in the MCLADW, the Regions' responsibilities include performing "an annual review of State/Tribal certification programs and proficiency testing results and monitor the adequacy of State/Tribal programs for certifying laboratories." This section reviews the documents and procedures used by the Region to perform these tasks.

2.1. Review of Regional Standard Operating Procedures for Assessing Primacy State Drinking Water Certification/Accreditation Programs

Region 3's Standard Operating Procedure (SOP) R3-QA810_4, named "Protocols for the Oversight and Evaluation of Region III State Drinking Water Certification and Accreditation Programs," was last updated on May 12, 2013. Management evaluated and approved the changes by early June 2013, and for many years, the SOPs have been co-signed by Division managers. The LCPM emphasized that this step has helped assure consistency, full documentation, and partnership in the program's work. The SOP contains the five administrative/programmatic elements listed in EPA's Guidance for Preparing Standard Operating Procedures (SOPs) (EPA-QA/G-6), including:

- Title Page;
- Table of Contents;
- Procedures, including the Purpose, Applicability/Scope, Summary of Procedure, Definitions, Personnel Qualifications/Responsibilities (identifying any special qualifications users should have such as certification or training experience and/or any individual or positions having responsibility for the activity being described); Criteria, checklists, or other standards that are to be applied during the procedure; and Records Management;
- Quality Control and Quality Assurance; and
- References.

The SOP is very detailed and precise. For example, the SOP describes unusually detailed steps for quality assurance and record-keeping. For each triennial review, the Region creates an Index file which tracks steps of the review or audit process and notes file names, descriptions, file formats, findings (if applicable), and when corrective actions (CAs) were verified. Items that are not retained are highlighted.

The SOP describes the approach used by the Region to implement the LCP and oversee its primacy agencies. The SOP has a thorough description of the information that should be collected during the SLCPA, the schedule and content of the report and a CA plan, and guidelines to track corrective actions taken by States. Once all CAs are deemed acceptable, the OSS generates a closeout letter which is shared with the State program office and the Region's WPS and EAID management chain. After the closing letter is submitted, all onsite assessment records are checked for completeness, using a checklist from the SOP. Communication protocols between the OSS, WPD Drinking Water Branch, and State COs are described to assure all materials and information have been relayed to and signed by the proper parties. The SOP also carefully cites all guiding documents and materials in the References section, as well as throughout the document, where appropriate.

2.2. Regional Personnel Qualifications/Responsibilities for Assessing Primacy State Drinking Water Certification/Accreditation Programs

The SOP clearly defines required qualifications, roles, and responsibilities of members of the Regional assessment team. The SOP also describes the WAL in Washington, DC and how the Region oversees the lab.

Region 3 WPD has performed a key role in setting and enforcing policies and requirements for Region 3's lab certifications and program accreditations. The program has provided much assistance and direction to Region 3 SLCPs through grants and by helping to assure necessary funding and staffing resources for SLCPs. WPD continues to provide funding for a part-time SEEP position for Mr. Long, who provides 0.5 full-time equivalent (FTE) to the program and is a critical component of the RLCP due to his long history of involvement.

The Region currently has adequate resources to oversee the SLCPs and complete SLCPAs, though would be strained by a need to audit any additional labs. (See discussion below about auditing satellite laboratories in a PSL network.) In addition to Mr. Long, approximately 0.4 FTE is allocated to the Regional LCPM, Mr. Messer. The team notes that Mr. Messer's allocation represents a reduction from resources provided for the previous LCPM, Joe Slayton.

Other Regional staff play an important role in the program. The LCPM and the EPA Regional Laboratory work well together, and the OASQA Associate Directors have continued to encourage CO training and experience for EPA Regional Lab analysts. The Region 3 Lab Director noted mutual benefits of the co-location of the LCP and the lab. The lab lends its COs to conduct PSL audits, and COs also answer technical questions from Region 3 States. Through these interactions, the lab staff gain insight into other lab practices. The LCP also benefits from access to the Region 3 COs, as highly trained technical staff are needed to perform the SLCPAs and PSL audits. Regional drinking water program managers in WPD are assigned to States and also work closely with the RLCP. They are invited to participate in the SLCPAs and lab audits, and routinely participate in opening and closing briefings. They always receive reports and correspondence.

When the former LCPM, Joe Slayton, retired, the program structure was reorganized and the position of LCPM was moved from the front office into the Technical Services Branch. Before the former LCPM retired, Mr. Messer spent nearly a year shadowing and learning his responsibilities. Also, strong support from Mr. Long, who worked closely with Mr. Slayton for many years, ensured a smooth transition.

Table 2.1 Area of Responsibility and Training Status of Regional Certification Officers

Name of Regional CO	Area(s) of Responsibility	Year Attended EPA CO Training	Year Last Audited EPA CO Training*
Ed Messer – Regional LCPM	Chemistry - Organic	1994	Never audited, past due
Jarmael Burman	Chemistry - Inorganic	2013	N/AP
Robin Costas	Chemistry - Inorganic	1991	Never audited, past due
Joseph Dorsey	Chemistry - Inorganic	1990	Never audited, past due
Eric Graybill	Chemistry Microbiology	2011 2013	N/AP N/AP
Jennifer Gundersen	Chemistry - Organic	2002	Never audited, past due

Name of Regional CO	Area(s) of Responsibility	Year Attended EPA CO Training	Year Last Audited EPA CO Training*
Annie Hilliard	Microbiology	2000	Never audited, past due
George Long	Chemistry	2006	Never audited, past due
Adam Molnar	Chemistry – Organic Chemistry - Inorganic	2013 2014	N/AP
David Russell	Microbiology	1997	2010, due
Susan Warner	Chemistry	1988	Never audited, past due

** The Region's response to the 2014 Annual Questionnaire noted that COs would attend refresher training when it is available remotely.*

As shown in Table 2.1, nearly all Regional COs are due to attend a refresher training. According to the MCLADW, COs should attend refresher training every five years. Most Regions attend the EPA CO course to ensure that they remain current with standard methods, get program and regulatory updates, interact and learn through peer contact with other COs, and ensure consistency across the country among Regions. Some TSC courses have been adapted to online training, but most training is offered in-person in Cincinnati, OH.

2.3. Regional Procedures for Assessing Primacy State Drinking Water Certification/Accreditation Programs

The Region 3 SOP closely adheres to requirements and procedures described for the Regional oversight of SLCPs in the MCLADW, but provides significantly more detail. The SOP also describes procedures for the Regional oversight of SLCPs accredited by the NELAC Institute (TNI) through its NELAP Accreditation Bodies (ABs).

Two States in Region 3 are NELAP ABs, including Pennsylvania (Department of Environmental Protection, or PA-DEP) and Virginia (Division of Consolidated Laboratory Services, or DCLS). Both States have dual drinking water programs. Region 3 personnel have joined the NELAP AB, New Jersey DEP, and participated in all of the NELAP Evaluation Teams for review of the NELAP programs. NELAP accreditation is fully voluntary in Pennsylvania, but State accreditation is mandatory. All commercial labs in Virginia performing compliance analysis are required to be NELAP-accredited, unless they limit their scope to drinking water. Under this special condition, the laboratory may be certified only by the State. Region 3 performs a separate evaluation for the non-NELAP portions of the two ABs. One helpful feature of the Region 3 SLCPA reports are tables which distinguish between NELAP and EPA requirements, observations about each program, and applicability of SOPs.

Table 2.2 Regional Oversight of SLCPs – Date of Last Assessment & Number of Laboratories In- and Out-of-State

State	SLCPA					Number of Laboratories Certified/Accredited In State (Out of State)			
	Agency	Assessor	Date of last SLCPA	Date of last signed certificate/report	Timely?[1]	Chem	Micro	Rads	*Crypto*
DC	N/A – implemented by the Region								
DE	DHSS	Region 3	October 25-26, 2012	November 27, 2012. Close-out January 20, 2013.	Yes	3 (13)[2]	2 (11)[2]	0 (4)[2]	0 (1)[2]
MD	MDE	Region 3	June 18-19, 2013	July 19, 2013. Close-out October 24, 2013.	Yes	29 (47)	38 (30)	1 (13)	0 (0)
PA	PA-DEP	Region 3	July 2014	July 30, 2014, final September 2014	Yes	36 (0)	115 (3)	0 (0)	NA[2] (0)
		NELAP Primary	July 2014 Ed and George participate (same week for both SDWA and TNI)	September 2014	Yes	17 (3)	20 (3)	2 (0)	NA[2] (0)
		NELAP Secondary	October 2011			2 (37)	1 (34)	1 (8)	1 (3)
VA	DCLS	Region 3	June 19 and 22, 2012	July 18, 2012. Close-out August 6, 2012	Yes	25 (29)	80 (18)	0 (6)	0 (0)
		NELAP Primary	June 20-22, 2012	Have copy of NELAP report Accredited by NJ NELAP Close-out July 31, 2012	Yes	10 (4)	18 (3)	1 (0)	0 (0)
		NELAP Secondary	June 20-22, 2012	No date found for report. Close-out July 31, 2012	Yes	0 (30)	0 (9)	0 (5)	0 (2)
WV[3]	DHHR	Region 3	September 20-21, 2012	October 13, 2012 Close-out February 12, 2013	Yes	4 (19)	23 (3)	0 (6)	0 (1)

[1]Timely is defined as at least triennially for EPA-certified LCPs and biennially for NELAC-accredited LCPs. Note: the timeframe is measured from the date of the signature on the previous assessment.

[2]State does not certify out-of-State labs, but issues "approval letters".

[3]No radiochemistry labs are certified in West Virginia. The program issues "approvals" based on reciprocity.

Note – EPA SLCPA dates are confirmed from copies of final reports, but didn't have NELAP reports.

Procedures followed during the Region 3 onsite triennial SLCPAs closely adhere to the Region's SOP, which is based on the MCLADW. In nearly all cases, the program review includes observation of the State COs performing an onsite laboratory assessment. (No observation was possible in Maryland, as the State had no backlog of audits. There were no scheduled assessments during the timeframe that the SLCPA needed to be performed to remain on the triennial schedule.) All required triennial reviews were completed, and files contained copies of reports, correspondence, and clear evidence that CAs and proper close-out actions were followed. NELAP ABs were not reviewed biennially, which is the TNI standard, but the assessments were conducted at least triennially, thereby fulfilling EPA requirements.

The area(s) of responsibility and training status of each State CO in Region 3 are listed in Table 2.3. EPA COs and NELAP Assessors are included. Note that no third party auditors are used in the Region.

Table 2.3 Area of Responsibility and Training Status of Certification Officers Utilized by Primacy States

Name/Affiliation of State Utilized Certification Officer	State	Area(s) of Responsibility	Year Passed EPA CO Training	Year Last Audited EPA CO Training
Christina Pleasanton	DE	Microbiology	2002	Never audited, past due
Brenda Haire	DE	Microbiology	2002	Never audited, past due
Charity Mabrey	DE	Microbiology	2009	Never audited, past due
Kevin Cottman	DE	Microbiology	2012	N/AP
Anthony Tata	DE	Chemistry (Inorganic) Chemistry (Organic)	2007 2008	Never audited, past due
Yaohong Zhang	DE	Chemistry (Inorganic)	2011	N/AP
Tara Lydick	DE	Chemistry	2013	N/AP
Linda Ames Massey, Program Manager	MD	Chemistry (Organic)	2008	N/AP
Xue-Qing Chen	MD	Chemistry (Inorganic)	2009	Never audited, past due
Tajammal Goodlow	MD	Microbiology	2011	N/AP
Aaren Alger, Program Chief	PA	Chemistry	2002 (NELAP)	Has not attended EPA training
Ronald L. Houck, Jr.	PA	Chemistry Microbiology Radiochemistry	2003 (EPA) 2004 (NELAP) 2004 (NELAP)	Never audited, past due Has not attended EPA training
Clare McCarthy	PA	Chemistry Microbiology	No date (NELAP)	Has not attended EPA training
Virginia M. Hunsberger	PA	Chemistry Microbiology	No date (NELAP)	Has not attended EPA training

Name/Affiliation of State Utilized Certification Officer	State	Area(s) of Responsibility	Year Passed EPA CO Training	Year Last Audited EPA CO Training
Thomas Kurtz	PA	Chemistry Microbiology	No date (NELAP)	Has not attended EPA training
Amy Hackman	PA	Chemistry Microbiology	No date (NELAP)	Has not attended EPA training
Yumi Creason	PA	Chemistry Microbiology	No date (NELAP)	Has not attended EPA training
Charles Decker	PA	Chemistry Microbiology	No date (NELAP)	Has not attended EPA training
Dwayne Burkholder	PA	Chemistry, Microbiology Crypto	2010 (NELAP) 2000 (EPA) 2010 (EPA)	Has not attended EPA training Never audited, past due N/AP
Corey Lewandoski	PA	Microbiology (In training), Chemistry	No date (NELAP)	Has not attended EPA training
Eric Nkurunziza (Note: as of date of audit, has resigned)	PA	In training	No date (NELAP)	Has not attended EPA training
Dewitt Casler	VA	Chemistry Microbiology	2010 (EPA) 2010 (NELAP)	N/AP Has not attended EPA training
Joseph Garman	VA	Chemistry Microbiology	2009 (EPA) 2009 (NELAP)	Never audited, past due Has not attended EPA training
Christina Lynchesky	VA	Chemistry Microbiology	2009 (EPA) 2009 (NELAP)	Never audited, past due Has not attended EPA training
Eileen Sanders	VA	Microbiology	1986 (EPA) No date (NELAP)	1990, past due
Ila Skinner	VA	Chemistry Microbiology	2010 (NELAP) 2010 (EPA)	Has not attended EPA training N/AP
Kay Smith	VA	Chemistry Radiochemistry	2006 (EPA) 2006 (NELAP)	Never audited, past due
Gregory W Young	WV	Chemistry (Organic) Radiochemistry	2003 2006 (NELAP)	Never audited, past due
Patrick L Marchio	WV	Chemistry (Inorganic)	2006	Never audited, past due
Mandie J. Simpson	WV	Chemistry (Inorganic)	2012	N/AP
Matthew B. Keaton	WV	Chemistry (Inorganic)	2012	N/AP
Thomas L. Ong	WV	Microbiology	1992	Never audited, past due
Tracy Goodson	WV	Microbiology	2003	Never audited, past due
Michael A. Flesher	WV	Microbiology	2004	Never audited, past due

Most States in the Region did not envision any concern about their ability to conduct reviews and the number of COs available to conduct and onsite audits. Mr. Burkholder is the only CO in Table 2.3 listed with microbiology certification in Pennsylvania. However, roughly half of the other COs in the State also are certified for microbiology and do some of certifications. Therefore, no concerns exist in this State.

West Virginia highlighted two possible concerns in the 2014 Annual Questionnaire. The State only has one CO for organic chemistry audits. Also, two analysts who passed the Inorganic

Certification Officers course in 2012 (Mandie Simpson and Matthew Keaton) need reclassification approval by the West Virginia Department of Personnel to be eligible to audit laboratories.

State COs are overdue for and should attend the EPA CO refresher training course. Most States have provisions in their SOPs for ongoing training which includes attendance at EPA CO training courses, when resources allow. Some States, including Virginia and Maryland, require all COs to complete either State-offered or NELAP Basic Assessor Training as well as technical training per discipline. However, Pennsylvania and Maryland COs are not required to attend the EPA CO courses, which raised concerns for the audit team.

If COs attend State-sponsored training, then Region 3 should confirm that the training is equivalent to the TSC course, which increases the Region's responsibility and liability for the training programs. The previous Region 3 LCPM helped develop course materials for and oversaw the State CO training programs in Maryland and Pennsylvania. This oversight is time-consuming, and the current LCPM noted that he could not review the records of state trainings or course materials during the most recent Pennsylvania SLCPA and he does not envision that he will have the resources needed to continue to provide the necessary level of review.

No concerns about funding or travel resources for laboratory audits were identified for the Region or States, unless all labs in the Maryland and West Virginia PSL networks must be visited for an onsite audit (see details in Section 3.4 below.).

The Region 3 SOP describes the schedule for tracking PTs for PSLs, which is described in detail in Section 3.4, below. In the Annual Questionnaire, Region 3 describes each SLCP's PT management approach and notes that each SLCP is considered effective. The State approaches for results tracking and addressing failures of PT studies include:

1. Results tracking: Delaware, Pennsylvania, and West Virginia track PT results data manually in an Excel spreadsheet. Pennsylvania is in the process of developing an automated tracking database. Maryland track results manually and electronically in the Accrediting Authority Management System (AAMS). Virginia tracks PT results in the DCLS LABCERT PROD database, which is a Laboratory Information Management System (LIMS) by STARLIMS.
2. After PT study failure: In Delaware, after two consecutive PT study failures, the laboratory is considered not certified for that analyte. In Maryland, a letter is sent to a laboratory after the first PT failure requesting the submission of an acceptable PT. T wo consecutive failures results in downgrading to provisional certification. During the following 90 days, the laboratory is required to perform Corrective Actions (CAs). In Pennsylvania, two consecutive PT study failures results in suspension. Virginia requires notification of CAs taken within 30 days after problematic PT sample results and a successful make-up PT study, but the State's approach if CAs were not met was not reported. After the first PT study failure, West Virginia requires laboratories to submit a CA report. After a second failure, the laboratory is downgraded to provisional certification and another CA report is requested. A West Virginia laboratory is decertified upon a third failure and an audit is required prior to recertification and before PTs are accepted.

Delaware, Pennsylvania, and West Virginia identified laboratory capacity or capability issues for some regulated drinking water contaminants in their responses to the Region's 2014 Annual Questionnaire. Delaware contracts analyses for pesticides, radionuclides and some volatile organic compounds (VOCs) to a certified laboratory. Pennsylvania noted a problem with PCBs as Decachlorobiphenyl by EPA 508A. West Virginia indicated multiple chemistry issues. The organic section is currently only certified for VOCs, THMs, EDB, DBCP, Glyphosate, and Carbonates. The laboratory has purchased several pieces of equipment for the remaining organics. A Demonstration of Capability study (DOC) has been started for HAA5s and the initial method development is beginning on EPA methods 505 and 550.1. Additionally, West Virginia noted that the Flame AA utilized for sodium analysis is antiquated (more than 20 years old) and the program is in the process of replacing it.

Reciprocity is permitted when a PSL utilizes a commercial laboratory for the analysis of SDWA compliance samples to complete its capabilities required for State primacy. The SOP explains that the commercial labs must be accredited by a NELAP program and a formal contract must be in place. The PSL must submit a table to the Region which lists the methods and analytes that are subcontracted. The SOP also includes a discussion of the process for certifying satellite laboratories within a State that participates in the PSL primacy network. More about these requirements will be discussed below, in Section 3.4.

The SOP includes templates for SLCPAs, including criteria and checklists to be used prior to the SLCPA, during the onsite visit, and during report development. The LCPM reviews State reports, CA plans, close-out letters, PT results, State SOPs, and QA and lab manuals, and confirms that the State has records of the certification status for any outside labs or satellite labs that provide analyses of SDWA contaminants required for State primacy. Copies of these materials were in the Region's files, along with correspondence between States and Region 3 on many topics, such as Method Detection Limits (MDL), DOCs, and CA plans.

As an example of thoroughness and strong oversight, Region 3's comments on State CA plans include detailed answers and suggestions on specific items. The Region used color coding to clarify which CAs were fully accepted and which required additional responses from the State. Subsequent correspondence showed that the Region ensured that the State completed the CA plans.

2.4. Regional Records Management for Assessing Primacy State Drinking Water Certification/Accreditation Programs

Records for SLCP reviews should be maintained in an easily accessible central location for a period of three years to include the last two onsite audits, or longer if required by specific State regulations. Region 3 retains files even longer, and all files are impeccable and well-organized. Mr. Long introduced a color-coding scheme which associates tab colors with a State, making it easy to retrieve materials. Folders are well-labeled and in chronological order, allowing for easy access to specific reports.

The Region uses a Document Control Number (DCN) system and prepares an index to catalog all materials collected and distributed within a year, including introductory letters for onsite reviews, pre-surveys, organizational charts, SLCP SOPs, QA manuals, Annual Questionnaires, SLCPA reports, assessment tools (e.g., checklists and spreadsheets), CAs, status update reports on

findings, and close-out letters. Materials for both EPA-certified and NELAP-accredited programs are found in the files. Each of these documents is in a separate folder. Logistical information, such as phone directories and floor plans, is also filed.

The Region also tracks progress in meeting program requirements and summarizes information across all States in the Region, which allows for a broader perspective of the SLCPs. Information is cross-referenced and organized to ensure all tasks are accomplished in a timely manner, such as dates of trips, lists of managers in all States, all PSL certifications, and organizational charts for all States.

3. Regional Oversight of Laboratories

The Regions oversee the certification of some laboratories. As Stated in the MCLADW, "Regional certification officers are responsible for the certification of the PSL in each Primacy State, and are also responsible for certifying all Tribal Nation laboratories and laboratories in non-Primacy States." This section reviews the documents and procedures used by the Region to audit and certify PSLs.

3.1. Review of Regional Standard Operating Procedure for Auditing Principal and Non-Primacy Laboratories

As discussed above in Section 2.1, Region 3 SOPs are detailed and thorough. Similar to the SLCPA SOP, the SOP for auditing PSLs includes checklists and templates, specifies detailed file management and recordkeeping practices, and outlines steps for generating reports, CA plans, and close-out procedures. Evidently the level of detail in the SOPs helped improve standardization and ensured completeness, for the audit records reviewed by the team were of high quality and similar in scope and detail.

The SOP for auditing PSLs contains the five administrative/programmatic elements listed in EPA-QA/G-6, including Title Page, Table of Contents, Procedures, Quality Control and Quality Assurance, and References. Each section has numerous steps and could serve as a model SOP for all Regional programs.

3.2. Regional Personnel Qualifications/Responsibilities for Auditing Principal State and Non-Primacy State Laboratories

The roles for the LCP staff and every member of the PSL audit team are specified in the SOP. The audits require highly technical staff and the skill level of the OSS, the SEEP, and the Regional lab staff is an invaluable asset which contributes significantly to the success of this program. Cooperation between the LCP staff and Regional lab staff is critical too, as the lab COs help with PSL audits and answer technical questions from States. Region 3 also reviews examples of contractor reports for the States and provides feedback on report content to complete documentation and to help with certification status decisions that must be made by the SLCP. The Region also reviews and comments on agreements or contracts with all commercial labs.

Neither the Region nor States use a third-party expert on their audit teams. Virginia does have a clause in their SOP to address this situation if it arises.

Region 3's LCP has adequate staffing to complete required PSL audits, under its current schedule, and sufficient COs to complete all lab audits and answer technical questions from PSLs. A potential resource problem may arise if the Region begins onsite audits at all satellite laboratories used by the PSLs (please see discussion in Section 3.3.).

3.3. Regional Procedure for Auditing Principal State and Non-Primacy State Laboratories

The procedures for the audits or oversight of NELAP-certified PSLs are clearly outlined in the Region's SOP R3-QA801_5, named "Region III Protocols for the Certification of Principal State Laboratories to Perform Drinking Water Analyses". The SOP is very thorough, and outlines model program requirements.

All Region 3 PSLs and State drinking water program offices are asked by OASQA to provide a listing of all satellite and commercial laboratories they utilize for drinking water analyses each year as part of their yearly PSL SDWA certificate package. Current certificates and contracts, agreements, or plans for emergencies also are collected. Region 3 assesses and certifies the PSLs in Delaware, Maryland, West Virginia, and also certifies WAL, as the Region has direct implementation authority over Washington D.C.

Both Maryland and West Virginia also have satellite labs that supplement the primary PSL and provide analytical capability needed for State primacy. For the NELAP-accredited PSL in Pennsylvania, the request for information about contracts and agreements, mentioned in the previous paragraph, is part of the "letter of recognition" package that the SOP outlines must be assembled for these labs. The Virginia PSL is operating under interim certification by Region 3, but will be accredited by the New Jersey NELAP AB for its next certification. In order to qualify for the letter of recognition, the PSL will be required to provide evidence of NELAP-accreditation.

When the PSL is not certified for a SDWA-required analyte, the Region also will issue letters of recognition to one of the State's satellite laboratories if it has been certified by the SLCP. This practice was adopted based on guidance included in a memo issued by Cynthia Dougherty on April 9, 2009. The SOP outlines the steps that Region 3 will follow for these satellite labs. During the SLCPAs, the file records for any State satellite laboratories will be reviewed. The Region always reviews the satellite lab's PT results; the onsite assessment report for the satellite lab prepared by the SLCP; associated CA reports from the satellite lab, if any; the letter of acceptance from the Certification Authority of the SLCP; the current scope of certification listed on the satellite lab's current certificate; procedures outlined in the appropriate SOPs and the satellite lab's QA manual for the PSL. If feasible, an onsite visit also will be conducted.

The SLCPs in Maryland (Maryland Department of the Environment, MDE) and West Virginia (West Virginia Department of Health and Human Resources, Bureau of Public Health, Office of Laboratory Services, or OLS) certify other labs in their PSL network. In West Virginia, the District Environmental Laboratory is certified by the SLCP, which is located within the same agency. West Virginia's Health laboratory is located in two locations (Big Chimney and Charleston, WV) and both locations are reviewed during the same onsite visit and issued a combined certificate. The team had no concerns about this procedure, as the Region's review of the State's certification was as thorough as a certification of a PSL described in the MCLADW.

In Maryland, the PSL is the Central Lab within the Maryland Department of Health & Mental Hygiene (MDHMH) located in Baltimore, Maryland. Region 3 certifies the Central Lab. MDE, which is a separate agency from MDHMH, certifies two MDHMH satellite labs that provide analytical capabilities as part of a PSL network with the Central Lab, including the Eastern Shore Regional Laboratory in Salisbury, MD and the Western Maryland Regional Laboratory located in Cumberland, MD. During its review of the Central Lab, Region 3 conducts the records review for the satellite labs. However, the Region does not visit the satellite labs because of the travel costs and time required due to the distance between labs. The Central Lab Director noted that adding these two site visits would be equivalent to adding another PSL to the RLCP's workload. The increased workload and additional travel costs likely could not be accommodated within the current budget for the RLCP.

The SOP also clearly explains what activities are performed by the Region for the non-primacy D.C. The Region certifies WAL. WAL performs the majority of analyses required for compliance monitoring in the District for the Washington Aqueduct public water supply. Neither the Region nor WAL perform SDWA certifications of commercial laboratories in the District. Rather, these commercial laboratories and any laboratories performing drinking water analyses for drinking water compliance samples are certified by other primacy States.

As noted above, Virginia's DCLS and PA-DEP laboratories are NELAP-accredited. Region 3 participates in the initial and final closing meetings of the NELAP onsite assessments of labs by teleconference. Region 3 also reviews the onsite assessment reports and CAs. In addition, Region 3 monitors PT study performance (see description below). Region 3 issues letters of recognition of NELAP AB certificates each year based on these reviews and after verifying use of approved methods.

A certificate, or letter of recognition for a NELAP-accredited PSL, is issued each December that lists: the date range over which the certificate applies (routinely January 1 until December 31st); each primacy critical parameter; and each method and the associated certification status. Region 3 is adjusting the schedule of recognition letters to better match the ABs' period of certification. Region 3 certificates include information on both the PSLs PT and onsite audit performance. The certificates are created from specified print areas within the electronic spreadsheets used to track PT results.

Last year, the Region developed standardized references for microbiology methods which helps to assure three-way confirmation, or that the methods reviewed during the onsite match the method reported on the PT and on the Region 3 certificates. This same approach across Region 3 is helping assure consistency for SLCPs. Uniformity is critical for a clear understanding that labs are certified for the methods used for drinking water compliance sample analyses.

The Region 3 SOP describes the process for tracking PT results for PSLs. The Region recommends that PSLs submit an early request for PT samples within the first calendar quarter, to ensure timeliness, and PSLs must complete their PT studies before the end of the third calendar quarter, to allow time for the certificates to be printed, signed, and sent. If the results are submitted in the fourth quarter, the Region will issue a second (reprinted) certificate to include the new PT sample result. For each sample, the Region requires labs to report the method, version number and standard method edition. The team noted that this information is carefully

reviewed in the Region, and noted a case where the Region detected that a PT study was completed using a non-SDWA method because the wrong version of the method was used. PT providers send PT results directly to Region 3 for all Region 3 PSLs. The hardcopy reports are retained in a notebook and, when full or every 2 years, the hard copies are archived to the Environmental Science Center's records rooms. Beginning three years ago the PT reports were also provided electronically using a spreadsheet with a specified format. The spreadsheets are retained on the shared LAN system.

The certificate lists the analyte name, whether the PT sample result was acceptable, certification status, method, onsite certification status, onsite method, and overall certification, which aligns with the Excel spreadsheet and simplifies the audit. If the PSL does not have analytical capability for an analyte, it will be indicated as "Not Reported" for the PT result and "Not Reviewed" for the onsite audit. In a separate certification binder for commercial labs, the Region tracks certification of labs contracted by the PSL. During onsite audits, the Region confirms that the PSL and these contracted labs complete the entire list of regulated contaminants.

The Region only tracks PT sample results and certification status for its list of regulated contaminants, which does not include all federal contaminants. For instance, the Region's list does not have contaminants regulated under the Stage 2 disinfectants/disinfection by-products rule or some radionuclides. (The Region only requires States to demonstrate capability and capacity for gross alpha, gross beta, Radium 226, Radium 228, and uranium.) Virginia requested to be certified for the other regulated radionuclides, but the Region would not provide the certification because the former LCPM did not concur that laboratory capacity for the analytes is required. Virginia and Pennsylvania used the New Jersey DEP NELAP AB to obtain the accreditation for the other radionuclides. However, the other Region 3 labs cannot demonstrate this capacity.

The SOP explains the process following an unacceptable PT result. Region-certified PSLs are allowed up to two additional tries to obtain an acceptable PT result after the initial failure. For every failure, the Region documents the root cause of the failure and what must be done in the future, so the problem can be checked in a future onsite visit. The Region downgrades the lab to provisional certification for that analyte and method, and issues a new certificate. If an alternative is available, as in the case where the Maryland PSL failed its PT study for method 515.3 but was already certified for method 515.4, the State may be issued provisional certification with restricted use. In this instance, the lab is instructed to use 515.3 only in situations where 515.4 was not an option. If the lab is unable to provide an acceptable result from those two makeup studies by October 1 of the year, they are downgraded to "not certified" for that analyte/method. NELAP-accredited PSLs are downgraded to "not certified" if they have unacceptable results for two consecutive PT studies. The Region issues reminder letters requiring CAs for PT failures and, if necessary, warnings not to continue with SDWA compliance analyses if PT failures result in loss of certification.

All Region 3's certificates and letters of recognition for NELAP-accredited PSLs highlight any analytes for which the PSL is not certified. Also the letters of recognition of NELAP AB certificates highlight any problems with the NELAP certificate. OASQA works with the PSLs and the State drinking water program manager to determine the labs that are utilized to perform analyses not covered by the PSL. This information, which includes current certificates for the

utilized labs, is retained on file. The gaps in coverage are checked to verify that the contracts/agreements/plans utilize NELAP-accredited labs or other State labs certified by EPA.

The Region maintains, prints, and stores a detailed log tracking progress on interim certification, noting all steps taken and the resolution, when relevant. The team noted appropriate use of the interim certification status in D.C., where the lab was issued interim certification for Readycult because it already had been certified by Region 3 for another method, and had submitted the method SOP, PT results, and data package. The Region followed up during the site visit a year later and issued full certification.

Table 3.2 Regional Oversight of Principal State Laboratories in Primacy States and Laboratories in Non-Primacy States – Laboratory, Location, Certification/Accreditation Entity & Date of Last On-site Audit

State/Territory Tribe/Other [1]	Laboratory Name (Location)	Laboratory Type [2]	Certification/Accreditation Entity [3] Date of Last On-site Audit			
			Chemistry	Microbiology	Radiochemistry	*Cryptosporidium*
District of Columbia (DC)	Washington Aqueduct Laboratory (WAL) (Washington, DC)	State	EPA Region 3 (IOCs, DBPs, VOCs) Last onsite 10/25-26/2011 Cert Expired 12/31/2014	EPA Region 3 Cert Expired 12/31/2014	EPA Region 3 (Uranium) Cert Expired 12/31/2014	N/A
	Eurofins Eaton, Analytical, Inc. (E Eaton) (Monrovia, Ca)	Commercial	CA ELAP (IOCs, DBPs, SOCs) Cert Expired 01/31/2014 VA VELAP (Dioxin) Cert Expired 06/30/2014	CA ELAP (Fecal Coliforms) Cert Expired 01/31/2014	CA ELAP Expired 01/31/2014	N/A
	Eurofins Lancaster Laboratories Environmental (E Lancaster) (Lancaster, PA)	Commercial	PA DEP NELAP (Dioxin) Cert Expired 01/31/2014	N/A	N/A	N/A
	Analytical Laboratory Services (ALS) (Middletown, PA)	Commercial	PA DEP NELAP (PCBs) Cert Expired 01/31/2014	N/A	N/A	N/A
Delaware (DE)	Delaware Public Health Laboratory (DPHL) (Smyrna, DE)	State	EPA Region 3 (IOCs, VOCs) Last onsite 10/23-24/2012 Cert Expired 12/31/2014	EPA Region 3 Last onsite 10/23-24/2012 Cert Expired 12/31/2014	EPA Region 3 (Uranium) Last onsite 10/23-24/2012 Cert Expired 12/31/2014	N/A
	Batta Laboratories, Inc. (Batta) (Newark, DE)	Commercial	NY SDH NELAP (Asbestos) Cert Expired 04/01/14	N/A	N/A	N/A
	QC Inc. (Southampton, PA)	Commercial	PA DEP NELAP (Total Nitrate and Nitrite) Cert expired 01/31/2015	N/A	N/A	N/A
	Pace Analytical Services (Pace-FL) (Ormond Beach, FL)	Commercial	FL DOH NELAP (DBPs, SOCs) Cert Expired 06/30/2014	N/A	N/A	N/A

State/Territory Tribe/Other [1]	Laboratory Name (Location)	Laboratory Type [2]	Certification/Accreditation Entity [3] Date of Last On-site Audit			
			Chemistry	Microbiology	Radiochemistry	*Cryptosporidium*
	Pace Analytical Services (Pace-PA) (Greensburg, PA)	Commercial	N/A	N/A	PA DEP NELAP Yes Cert Expired 03/31/2014	N/A
	Underwriters Labs LLC (UL LLC) (South Bend, IN)	Commercial	FL DOH NELAP (Dioxin) Cert Expired 06/30/14	N/A	N/A	N/A
	Analytical Laboratory Services (ALS) (Middletown, PA)	Commercial	PA DEP NELAP (PCBs) Cert Expired 01/31/2015	N/A	N/A	N/A
Maryland (MD)	Maryland Department of Health and Mental Hygiene – Central Regional Laboratory (Baltimore, MD)	State	EPA Region 3 (IOCs, DBPs, VOCs, SOCs) Last onsite 06/11-12/2013 Cert Expired 12/31/2014	EPA Region 3 Last onsite 06/11-12/2013 Cert Expired 12/31/2014	EPA Region 3 Last onsite 06/11-12/2013 Cert Expired 12/31/2014	N/A
	Maryland Department of Health and Mental Hygiene – Eastern Shore Regional Laboratory (Salisbury, MD)	State	EPA Region 3 (IOCs, DBPs, VOCs, SOCs) Recognized by reciprocity	EPA Region 3 Recognized by reciprocity	EPA Region 3 Recognized by reciprocity	N/A
	Maryland Department of Health and Mental Hygiene – Western Regional Laboratory (Cumberland, MD)	State	EPA Region 3 (IOCs, DBPs, VOCs, SOCs) Recognized by reciprocity	EPA Region 3 Recognized by reciprocity	EPA Region 3 Recognized by reciprocity	N/A
	Batta Laboratories, Inc. (Newark, DE)	Commercial	NY SDH NELAP (Asbestos) Cert Expired 04/01/14	N/A	N/A	N/A
	Analytical Laboratory Services (ALS) (Middletown, PA)	Commercial	PA DEP NELAP (DBPs, SOCs, PCBs) Expired 06/30/2014	N/A	N/A	N/A
	Eurofins Eaton, Analytical, Inc. (Monrovia, Ca)	Commercial	CA ELAP (Dioxin) Cert Expired 01/31/2015	N/A	N/A	N/A
Pennsylvania (PA)	Pennsylvania Department of Environmental Protection Bureau of Laboratories (PA BOL)	State	PA DEP NELAP (IOCs, DBPs, VOCs, SOCs,) Cert expires 03/31/2015 NJ DEP NELAC Cert Expired 06/30 2014	PA DEP NELAP Cert expires 03/31/2015	PA DEP NELAP Cert expires 03/31/2015	N/A

State/Territory Tribe/Other [1]	Laboratory Name (Location)	Laboratory Type [2]	Certification/Accreditation Entity [3] Date of Last On-site Audit			
			Chemistry	Microbiology	Radiochemistry	*Cryptosporidium*
	RJ Lee Group (Monroeville, PA)	Commercial	PA DEP NELAP (Asbestos) Cert expired 04/30/2014	N/A	N/A	N/A
	Analytical Services (Brockway, PA)	Commercial	PA DEP NELAP (Free cyanide) Cert expired 09/30/2013	N/A	N/A	N/A
	Analytical Laboratory Services , Inc. (ALS) (Middletown, PA)	Commercial	PA DEP NELAP (Total Nitrate and Nitrite, PCBs) Cert expired 01/31/2014	N/A	N/A	N/A
	Eurofins Lancaster Laboratories Environmental (E Lancaster) (Lancaster, PA)	Commercial	PA DEP NELAP (Dioxin) Cert expires 01/31/2014	N/A	N/A	N/A
Virginia (VA)	Virginia Division of Consolidated Laboratory Services (VA DCLS).	State	NJ DEP NELAP Cert expired 06/30/2014	NJ DEP NELAP Cert expired 06/30/2014	NJ DEP NELAP Cert expired 06/30/2014	N/A
	Wisconsin State Laboratory of Hygiene	State	FL DOH NELAP (Asbestos) Cert expired 06/30/2014	N/A	N/A	N/A
	West Virginia Department of Health and Human Resources Bureau of Public Health	State	EPA Region 3 (Free cyanide) Last onsite 09/18-19/2012 Cert expired 12/31/2013	N/A	N/A	N/A
	Pace Analytical Services (Minneapolis, MN)	Commercial	MN DOH ELAP (Dioxin) Cert expired 12/31/2013	N/A	N/A	N/A
	Pennsylvania Department of Environmental Protection Bureau of Laboratories (PA BOL)	State	NJ DEP NELAC (Endothall, Glyphosate) Cert Expired 06/30 2014	N/A	N/A	N/A
	Analytical Laboratory Services , Inc. (ALS) (Middletown, PA)	Commercial	PA DEP NELAP (PCBs) Cert expired 06/14/2014	N/A	N/A	N/A
West Virginia (WV)	West Virginia Environmental Chemistry Laboratory (Big Chimney WV)	State	EPA Region 3 (IOCs, VOCs) Last onsite 09/18-19/2012 Cert expired 12/31/2014	EPA Region 3 Last onsite 09/18-19/2012 Cert expired 12/31/2014	N/A	N/A

State/Territory Tribe/Other [1]	Laboratory Name (Location)	Laboratory Type [2]	Certification/Accreditation Entity [3] Date of Last On-site Audit			
			Chemistry	Microbiology	Radiochemistry	*Cryptosporidium*
	West Virginia Office of Laboratory Services (Charleston, WV)	State	N/A	EPA Region 3 Last onsite 09/18-19/2012 Cert expired 12/31/2014	N/A	N/A
	Analytical Laboratory Services , Inc. (ALS) (Middletown, PA)	Commercial	PA DEP NELAP (PCBs) Cert expired 06/14/2014	N/A	N/A	N/A
	Eurofins Eaton, Analytical, Inc. (Eurofins Eaton) (Monrovia, Ca)	Commercial	CA ELAP (Asbestos) Cert expired 01/31/2014	N/A	N/A	N/A
	Underwriters Labs LLC (UL LLC) (South Bend, IN)	Commercial	FL DOH NELAP (DBPs, SOCs) Cert Expired 06/30/14	N/A	FL DOH NELAP Cert Expired 06/30/14	N/A

The certification status (e.g., decertified, provisional, interim, renewal, certified but inactive) for each primacy agency was noted in the Annual Questionnaire and is discussed below:

Delaware: No laboratories have been decertified. Delaware downgrades the lab to provisional certification for any analyte with an unacceptable PT sample result. Only one lab, Mid-Atlantic Environmental Laboratories, has received a provisional certification, for 1 of 60 total analytes.

Maryland: No laboratories have been decertified in the past year, although two labs were downgraded to provisional certification after unacceptable PT sample results, including Baltimore County Bureau of Utilities, Engineering & Regulation Lab (MD Lab ID # G-150)-PTs for THMs and Reliance Laboratories-Bridgeport (WV)-PTs for VOCs and THM.

Pennsylvania: PA-DEP does not use provisional certification as an accreditation status. Many laboratories have been suspended for various fields of accreditation based on PT sample result failure. Accreditations are reinstated when the laboratory successfully performs a PT for the suspended analyte.

Virginia: No labs have been provisionally certified or decertified in the past year.

West Virginia: The State reported only one change—Reliance Laboratories switched from an electrode (free cyanide) to a colorimetric (total cyanide) method.

The SOP specifies the steps to track certification status and issuance of certificates for PSLs, and implementation of these steps is excellent. Every lab had a certificate, which noted the analytes and methods that were certified and the certificate expiration date. The data are carefully tracked, and the process has redundancy. Each year the Region performs an internal record audit on general records, and confirms that audit checklists and any interim certifications are complete and filed correctly. Certificates for PSLs are issued and filed before December 31, but certificates for commercial labs, if contracted by the PSL, are not filed until the end of the first quarter of the year. Certificates and the SOP indicate that certification can be withdrawn anytime during the three-year period if the laboratory fails to demonstrate a continued ability to successfully pass annual PT studies.

The SOP describes steps to take prior to the lab audit, during the onsite visit, when preparing the report and reviewing the CA plans, and to close-out. Several additional steps taken by the LCPM when conducting audits stand out. Prior to the lab audit, Region 3 sends a very detailed pre-survey questionnaire to the States, marks any questions generated by the State response, and also populates a checklist that is completed during the site visit. While on site, the LCPM tries to interview State COs in their own office to build trust and relationships.

The team noted that the information is extremely detailed, and the questionnaires and checklists contained notes from the auditors to ask follow-up questions during the audit. Similarly, CA plans were reviewed carefully by the Region, and recommended changes were tracked to ensure implementation. Documentation shows that States keep the Region apprised of program and staff changes, equipment malfunctions, and plans to enhance or retain laboratory capabilities such as capital funding plans for new equipment or contracts with commercial labs. As an example of the Region’s thoroughness, an extra step was required by the Region for the West Virginia CA plan. The plan required preparation and updates to SOPs, and the Region required the State to notify

labs of the new requirements and to update the State website. In another example, the Region integrated findings from the PSL audit into Delaware's SLCPA to facilitate communication and to ensure that both PSL and SLCP staff were aware of Regional concerns and findings.

3.4. Regional Records Management for Auditing Principal State and Non-Primacy State Laboratories

Records for the last two onsite PSL audits should be maintained in an easily accessible central location for a period of 3 years, or longer if required by State regulations. The Region 3 SOP specifies retention and location of Regional files, and specifies to maintain at least the two most recent audits in the files with overflow records stored elsewhere. Records are maintained for longer than the six years specified in the MCLADW.

As described above for the RLCPA files, audit files have color-coding, chronological filing, and explicit file-labeling which allow for high-level organization. Individual files exist for all onsite reports by categories (e.g., inorganic chemistry, organic chemistry, microbiology, and radiochemistry), certificates (such as letters recommending provisional or interim certification), CA reports from the PSLs, status update reports on findings, additional correspondence (as necessary) and close-out letters. For interim PSL certifications, a log of materials requested by the Region is tracked to note when materials are received. Files for separate elements are maintained, including SOPs, equipment, MDL summaries, DOC study summaries, personnel information, and materials mentioned above. PT results are in separate binders, which use the same color coding as the files. Notes and notebooks used by auditors during the onsite visit are included in the files.

4. Regional Communication and Technical Assistance

The Region's oversight of the SLCPs includes providing technical assistance to the States. As stated in the MCLADW, the Region's responsibilities include "(sponsoring) annual meetings for the State COs and (providing) technical assistance to the States' EPA-certified drinking water laboratories, as needed." This section reviews the Regions' performance of these tasks.

4.1. Regional Communication

As described above, the EAID and WPD coordinate the Region's program for PSL certification and oversight of SLCPs. There is no set schedule of meetings between the EPA WPD drinking water program managers in Philadelphia and the PSL and laboratory staff at Fort Meade, but communication by frequent email and phone call occur when issues or questions arise.

As stated earlier in Section 2.1, for many years the SOPs for conducting this work have been co-signed by both Division managers. WPD Drinking Water Program Managers for each Region 3 State are invited to participate in onsite assessments of PSLs. The Program Managers routinely participate via conference call during the opening and closing sessions of the PSL audit. All State laboratory certification reports, annual PSL certificates, and yearly status summaries are also shared with the Drinking Water Branch. These measures have helped assure consistency, full documentation, and partnership.

The WPD has performed a key role in setting and enforcing policies and requirements in Region 3 with regard to lab certification/accreditation. The program has provided much assistance and

direction to SLCPs through grants and helping assure the necessary funding and workforce. Currently, the WPD funds a SEEP position within the EAID for implementation of this work.

As recommended in the MCLADW, Region 3 hosts an annual meeting of all of the States under their purview to provide program and regulatory updates and to discuss any concerns of SLCPs, and encourages at least one CO from each State to attend. The December 17, 2014 teleconference meeting was attended by at least one representative from each State, Regional staff, and representatives from TSC who were presenting updates and sharing program information. However, a representative from D.C. canceled attendance due to a city-wide drinking water emergency. Region 3 develops agendas for these meetings and creates an attendance list. Both documents for the December 2014 meeting were provided to the team for review.

In addition, the WPD Drinking Water Program Managers participate in conference calls and meetings with their States, as noted below:

Delaware: The Region has quarterly meetings scheduled by Health Systems Protection Section Chief, Thom May.

Maryland: The Region meets regularly with the State drinking water program staff and is kept abreast of all relevant regulatory issues.

Pennsylvania: On an as-needed basis, the PA-DEP NELAP AB personnel contacts the WPD drinking water program staff for input.

Virginia: In-person meetings with Regional certification/accreditation staff and VDH-ODW staff are planned on an as-needed basis. Phone or e-mail contact is made as needed.

West Virginia: No meetings are scheduled on a routine basis, but phone or e-mail contact is made as needed.

4.2. Regional Technical Assistance

The team complimented the Region on its outreach and assistance to its States and noted that the Regional laboratory COs willingly answer technical questions for the Region 3 PSLs, providing thoughtful and accurate answers.

5. Assessment Summary

5.1. Commendations

The team commends Region 3 for its strong cooperation between the Regional Laboratory, the RLCP, and the WPD program staff. This bridge is formally established through SOPs that have been co-signed by both Division managers, and facilitated through frequent communication and shared documents that illustrate program status, such as the SLCPA and PSL audit reports, CA plans, close-out reports, and annual PSL certificates.

Regional recordkeeping is outstanding and fully complies with the MCLADW requirements. Records are impeccable and well-organized by State. The team particularly commends that the Region also summarizes and tracks information across all States in the Region, creating a higher level of organization and ability to draw conclusions for Region-wide comparisons.

Contributions from the highly skilled COs in the LCP and Regional Laboratory are essential for the success of this complicated and technical program. The team commends the careful tracking by the LCP staff and frequent communication and follow-up with the States to ensure all steps for SLCPAs and lab audits are completed through close-out. Annual meetings with the State COs to provide regulatory and technical updates also keep States current. The team noted that both LCP and Region 3 laboratory COs helpfully answer technical questions, rather than referring questions to TSC. These actions build the State/Regional relationship and improve Regional oversight of the SLCPs.

All SLCPAs and most PSL audits are timely and meet the triennial review requirements. The team particularly commends that the time from the onsite portion of these reviews to the close-out of each project is carefully monitored to meet the timeframes outlined in the Region's SOPs.

The team commends the Region's participation in the assessments and PSL audits for the two states accredited by the New Jersey DEP NELAP AB, Pennsylvania and Virginia. The Region attends all entrance and closing interviews, reviews reports, offers comments on CA plans, and, once close-out is completed, issues recognition letters on top of the NELAP certificates.

Tracking of coverage to affirm that all PSLs have capability or have contracts for analysis of all contaminants on the Region's list of regulated contaminants is excellent. Every lab has a certificate, and certificates are carefully tracked and well-documented.

Tracking of PT sample results and issuance of annual certificates is excellent. The team commends the Region's practice of encouraging labs to request PT studies from the PT providers during the first calendar quarter and submit samples to the Region by the third calendar quarter. This timetable helps the Region track compliance with the annual requirement to complete satisfactory studies and allows time to repeat studies when results are unsatisfactory.

5.2. Recommendations/Action Items

The following items are suggested action items aimed at strengthening the program in Region 3. These items are not deficiencies and do not require CAs; they are simply suggestions.

5.2.1. **Repeat Recommendation**

None.

5.2.2. **New Recommendation**

1. The current LCPM spent approximately one year shadowing and learning the LCPM's job from his predecessor and Mr. Long. The team recommends that Region 3 institutionalize this succession planning strategy.

2. The team recommends that all COs in the Region and Region 3 States be encouraged to attend the EPA CO courses for refresher training. The MCLADW recommends training every five years. However, no COs have attended refresher training in the past five years and some have not attended training since the early 1990s, when the microbiology methods were altogether different. The time and resources required to travel to a TSC-provided CO course are an impediment to some Region 3 States. During the exit briefing, the team and Region 3 discussed the possibility of having Region 3 host the CO training at the Region 3 lab. (TSC will offer the CO course in different locations if a host lab can be found, and rotates periodically from the east to west coast.)

5.3. Findings/Corrective Actions

The following items are considered deficiencies in the Region 3 program and require CA; CAs must be submitted to OGWDW and documented upon completion.

5.3.1. **Repeat Finding**

None.

5.3.2. **New Finding**

1. The team could not confirm that the Region ensures that State-based CO training meets the requirements of the MCLADW. Most Regions and States send COs to the EPA CO course, but Pennsylvania and Maryland offer their own CO training courses. Region 3 is responsible for ensuring that all COs in the Region and Region 3 States are properly trained, but the LCPM confirmed that they do not have the time to review records or training materials to confirm the quality of the State-sponsored training courses during the SLCPAs. The team's concern was elevated during this review because the team reviewed one Maryland lab audit report which demonstrated substandard wording and observations: if the CO had produced this material during the TSC course, they would not have passed the lab mock-up portion of the training.

2. The approach for the Region's accreditation of the satellite PSLs in Maryland and West Virginia was questioned by the review team. The team confirmed that the Region must conduct audits for all laboratories included in the PSL network, and cannot rely on the SLCP to certify a lab as the PSL for some analytes as has been done in Maryland and West Virginia. In both States, Region 3 has permitted the SLCP to certify satellite labs as a PSL and recognized MDE certification through reciprocity. During the primary PSL onsite audit, Region 3 reviews the SLCP's records for satellite lab certification, but Region 3 does not conduct the onsite portion of a satellite audit in Maryland. The team affirmed that Region 3 cannot delegate the certification process and must certify all labs in the PSL network. Note that other Regions with similar organizational structures within a State's PSL network, such as Region 4 and Region 5, conduct onsite lab audits of all laboratories in the network. The Lab Director noted that completing the onsite portions of the audits would impose a significant resource burden, as the labs are not close to the primary PSL lab and the audit team would have to extend their trip to cover this additional work.

3. The Region must ensure that it audits or issues a letter of recognition for all SDWA-regulated contaminants and methods, including the Stage 2 DBPR contaminants and all radionuclides listed in the CFR. TSC offers contract assistance to audit radionuclides labs, so the Region may ask for this assistance, if needed, or recognize NELAP accreditation.

6. Signatures

Judith A. Brisbin — 1-8-2016

OGWDW, TSC Lead Assessor — Date

TSC Laboratory Certification Team Leader

Judith A. Brisbin, Ph.D.

Michella Karapondo — 1-8-16

OGWDW, TSC Assessor — Date

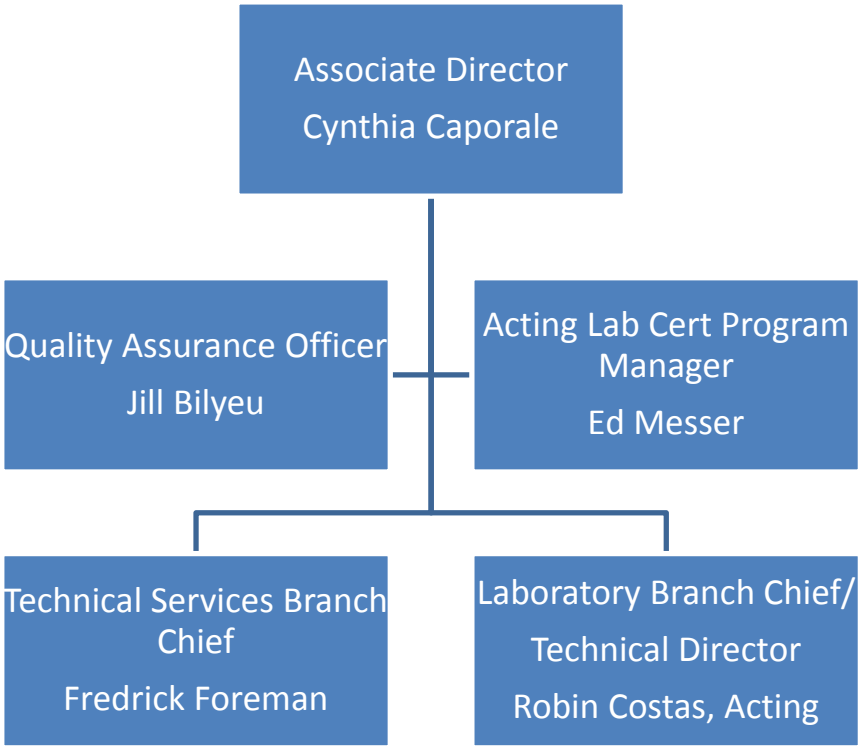
Michella Karapondo

Daniel P. Hautman — 1/8/16

OGWDW, TSC Deputy Director — Date

Daniel P. Hautman

Attachment A. Region 3 Laboratory Certification Program Organizational Chart



Attachment B. Agenda for Month Year Region 3 RLCPA

Regional Review – Region 3 Lab Cert Program			
Tentative Agenda			
Thursday February 5, 2015		Location	Invitees
9:00 AM – 10:00 AM	Opening Conference at Region 3 Laboratory		Ed Messer, Judy Brisbin, Michella Karapondo, Jennifer Best, Dan Hautman, Laurie Potter - Cadmus
10:00 AM – 12:00 PM	Region 3 file review		Judy, Michella, Jennifer, Dan & Cadmus
12:00 PM – 1:00 PM	Lunch		
1:00 PM – 5:00 PM	Continue Region 3 file review		Judy, Michella, Jennifer, Dan & Cadmus
Friday February 6, 2015			
9:00 AM – 12:00 PM	Continue Region 3 file review		Judy, Michella, Jennifer, Dan & Cadmus
12:00 PM – 1:00 PM	Lunch		
1:00 PM – 2:00 PM	Summarize assessment findings		Judy, Michella, Jennifer, Dan & Cadmus
2:00 PM – 3:00 PM	Wrap up/Review of Findings		Ed, Judy, Michella, Jennifer, Dan, Cadmus, Others?

Attachment C. Attendees at the February 2015 Region 3 RLCPA

	Participant	Program	Role	Meeting
1.	Cynthia Caporale	US EPA Region 3	Associate Director, OASQA	Entrance/Exit Meetings
2.	Fred Foreman	US EPA Region 3	Technical Services Branch Chief, OASQA	Entrance/Exit Meetings
3.	Ed Messer	US EPA Region 3	OSS, OASQA	Entrance/Exit Meetings
4.	George Long	US EPA Region 3	SEEP assigned to LCP	Entrance/Exit Meetings
22.	Daniel Hautman	US EPA OGWDW/TSC	TSC Assessment Team	All
23.	Judith Brisbin	US EPA OGWDW/TSC	TSC Lead Assessor	All
24.	Jennifer Best	US EPA OGWDW/TSC	TSC Assessment Team	All
25.	Michelle Karapondo	US EPA OGWDW/TSC	TSC Assessment Team	All
26.	Laurie Potter	Cadmus	Contractor for RLCPA	Entrance/Exit Meetings